



Department of Energy

Washington, DC 20585

OCT 18 2002

QA: N/A

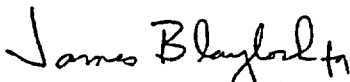
M. R. Arenaz, Program Manager
National Spent Nuclear Fuel Program
U.S. Department of Energy
Idaho Operations Office
850 Energy Drive
Idaho Falls, ID 83401-1563

ISSUANCE OF DEFICIENCY REPORT(S) (DR) EM(O)-03-D-004 THROUGH EM(O)-03-D-007 RESULTING FROM THE OFFICE OF QUALITY ASSURANCE (OQA) AUDIT EM-ARC-02-10

Enclosed are DRs EM(O)-03-D-004 through EM(O)-03-D-007 generated as a result of OQA
Audit EM-ARC-02-10.

Please provide responses to these deficiencies that meet the applicable requirements of
Administrative Procedure (AP) 16.1Q, *Management of Conditions Adverse to Quality*. Send the
original of your responses to Deborah G. Opielowski, Navarro Quality Services,
P.O. Box 364629, Mail Stop 455, North Las Vegas, Nevada 89036-8629. Initial response to the
DRs is due ten working days from the date of this letter. Any extension to the due dates must be
requested in accordance with AP-16.1Q.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or
John R. Doyle at (702) 794-5021.


R. Dennis Brown, Director
Office of Quality Assurance

OQA:JB-0102

Enclosures:

1. DR EM(O)-03-D-004
2. DR EM(O)-03-D-005
3. DR EM(O)-03-D-006
4. DR EM(O)-03-D-007



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NM5507
WM11

M. R. Arenaz

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OCT 18 2002

cc w/encl:

R. A. Milner, DOE/HQ (RW-2), FORS

N. K. Stablein, NRC, Rockville, MD

Robert Latta, NRC, Las Vegas, NV

S. E. Archuleta, NQS, Las Vegas, NV

P. V. Auer, NQS, Las Vegas, NV

J. R. Doyle, NQS, Las Vegas, NV

W. J. Glasser, NQS, Las Vegas, NV

D. G. Opielowski, NQS, Las Vegas, NV

B. M. Terrell, DOE/YMSCO, Las Vegas, NV

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8. ☒ Deficiency Report
☐ Corrective Action Report

No EM(O)-03-D-004

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document (Document ID and Revision or Date)

DOE/RW-0333P, Revision 12, *Quality Assurance Requirements and Description*
(QARD)

2. Related Report No.:

EM-ARC-02-10

3. Responsible Organization

National Spent Nuclear Fuel Program (NSNFP)

4. Discussed With:

Don Arnold, Bob Blyth

5. Requirement.

- a) QARD, Section III.2.6.F requires that "Technical review through publication in a referred professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following"
- b) QARD Supplement I.2.1A requires that software acquisition, development, modification and maintenance to proceed "in a planned, traceable and orderly manner utilizing a defined software life-cycle methodology."
- c) QARD Supplement III.2.6.A requires in part, "Model development and approaches to validation shall be planned, controlled, and documented."

(Continued on page 2)

6. Description of Condition.

- a) Contrary to the above requirement, NSNFP procedure PSO 3.03, Revision 1, *Engineering Analysis*, 01/15/2002, Section III.B.1.b.4, allows model validation using a "technical review through publication in open literature" without corroboration. NSNFP is generating technical reports, e.g., DOE/SNF/REP-071, Revision 1 and DOE/SNF/REP-078 (draft), which indicate in their respective summary and analysis plan that a model is documented.
- b) Contrary to the requirement, NSNFP Procedure PSO 19-01, Revision 1, *Software Control*, 1/25/2002, Section II, does not provide a methodology to implement the requirement.
- c) Contrary to the requirement, NSNFP Procedure PSO 3.03, Revision 1, 1/25/2002, Section III.B, does not provide a methodology to implement the requirement.

(Continued on page 2)

Has work been stopped? ☐ Yes ☒ No

7. Initiator.

Patrick V. Auer

Printed Name

Signature

Date

9. Does a stop work condition exist?

☐ Yes ☒ No ☐ N/A

If Yes, Check One

☐ A

☐ B

☐ C

☐ D

10. Recommended Actions

None.

11. QAR Review.

Patrick V. Auer

Printed Name

Signature

Date

12. Response Due Date.

10 Working days after issuance

13. QAM Issuance Approval:

R. Dennis Brown

Printed Name

Signature

Date

14. Corrective Actions Verified/Closure.

QAR Printed Name

Signature

Date

15. QAM Closure Approval

Printed Name

Signature

Date

Template AP161-1

Rev 3/25/02

ENCLOSURE 1

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☒ DR/CAR/QO
☐ SWO

No: EM(O)-03-D-005

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

5. Requirement: (Continued)

- d) QARD, Supplement III.2.6.B.6 requires a "discussion of mathematical and numerical methods that are used in the model, including governing equations, formulas, and algorithms, and their scientific and mathematical bases."
- e) QARD, Section 2.2.10.C states, "The review shall be performed by individuals other than the preparer."

6. Description of Condition: (Continued)

- d) Contrary to the requirement, NSNFP procedure PSO 3.04, *Engineering Documentation*, Attachment A, does not provide guidance or methodology to require the procedure user to provide the required information.
- e) Contrary to the requirement, NSNFP Procedure PMP-6.01, Revision 6, *Review and Approval of NSNFP Internal Documents*, does not address the requirement. For example, during the review of QAPP-001, Revision 01, the originator was identified on the Document Review Transmittal as a mandatory reviewer.

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No EM(O)-03-D-005

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QA QA

DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1 Controlling Document (Document ID and Revision or Date)

National Spent Nuclear Fuel Program (NSNFP) PMP 7.01, Revision 0,
01/15/2002

2. Related Report No.

EM-ARC-02-10

3 Responsible Organization:
NSNFP

4 Discussed With:
Bob Blyth, Don Armour

5 Requirement

PMP 7.01, *Quality Program Acceptance for DOE SNF Sites*, Section III.B.2.f requires in part "... based on satisfactory resolution of inconsistencies identified in a desk top review and if surveillance/audits are used, prepare correspondence for NSNFP QAPD approval indicating the acceptance of the DOE SNF Site QA program."

6 Description of Condition

Contrary to the above requirement, a memorandum was issued from R. Blythe to P. Dirkmaat, September 5, 2002, conditionally qualifying the INEEL Spent Nuclear Fuel Program to RW-0333P. Additionally, the memo identifies that there are approximately 15 findings adverse to quality, and provides "interim guidance" for corrective measures.

Has work been stopped? ☐ Yes ☒ No

7. Initiator.

Patrick V. Auer

Printed Name

Signature

Date

9 Does a stop work condition exist?

☐ Yes ☒ No ☐ N/A

If Yes, Check One

☐ A

☐ B

☐ C

☐ D

10 Recommended Actions:

None.

11. QAR Review.

Patrick V. Auer

Printed Name

Signature

Date

12 Response Due Date

10 Working days after issuance.

13 QAM Issuance Approval

R. Dennis Brown

Printed Name

Signature

Date

14 Corrective Actions Verified/Closure

15 QAM Closure Approval

QAR Printed Name

Signature

Date

Printed Name

Signature

Date

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WASHINGTON, D.C.

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8. ☒ Deficiency Report
☐ Corrective Action Report

No EM(0)-03-D-006

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)

DOE/RW-0333P, Revision 12, *Quality Assurance Requirements and Description* (QARD)

2. Related Report No.:

EM-ARC-02-10

3. Responsible Organization:

National Spent Nuclear Fuel Program (NSNFP)

4. Discussed With:

Neal MacKay, Chris Dahl, Rob Batten

5 Requirement

QARD, Section V.1 states in part, "This supplement applies to processes and controls for the management of data that either exist or are used in an electronic format. This includes electronic formatted data used in design input, developed as design output, or developed as an output of scientific investigation or performance assessment modeling analysis."

6 Description of Condition:

INEEL personnel using the Goth_SNF Software Program routinely transfer electronic files from a computer workstation to a PC and vice versa. The NSNFP does not have process controls in the form of an implementing procedure to address the requirements of Supplement V of the QARD.

Has work been stopped? ☐ Yes ☒ No

7. Initiator:

Samuel E. Archuleta *Samuel E. Archuleta* 10-8-02

Printed Name

Signature

Date

9 Does a stop work condition exist?

☐ Yes ☒ No ☐ N/A

If Yes, Check One

☐ A

☐ B

☐ C

☐ D

10 Recommended Actions

NONE

11 QAR Review

Samuel E. Archuleta 10-8-02

Printed Name

Signature

Date

12 Response Due Date

10 Working days after issuance

13 QAM Issuance Approval

R. Dennis Brown

James Blyford Jr

10/17/02

Printed Name

Signature

Date

14 Corrective Actions Verified/Closure:

15. QAM Closure Approval

QAR Printed Name

Signature

Date

Printed Name

Signature

Date

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8 ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION
REPORT

NO. EM(O)-03-D-007

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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document (Document ID and Revision or Date)

Quality Assurance Staff Procedure (QAS) 16 02, Revision 6, *Corrective Action*

2 Related Report No :

EM-ARC-02-10

3 Responsible Organization

National Spent Nuclear Fuel Program

4 Discussed With

Robert Blyth

5 Requirement

QAS 16 02, paragraph III, E 2, states in part. "For significant conditions adverse to quality, perform the following additional steps . . . "Submit the root cause analysis documentation with the CAR response "

6 Description of Condition:

Contrary to the above requirement, no root cause analysis was performed and as a result documentation was not submitted with the response to Corrective Action Report 02-NSNF-AU-001-CAR-001.

Has work been stopped? ☐ Yes ☒ No

7 Initiator

John R Doyle  10/08/02
Printed Name Signature Date

9 Does a stop work condition exist?

☐ Yes ☒ No ☐ N/A
If Yes, Check One ☐ A ☐ B ☐ C ☐ D

10 Recommended Actions

None

11 QA Review

John R Doyle  10/02/02
Printed Name Signature Date

12. Response Due Date

10 Working Days after Issuance

13 QAM Issuance Approval

Printed Name R. Dennis Brown

Signature



Date 10/17/02

14 Corrective Actions Verified/Closure

15. QAM Closure Approval

QAR Printed Name Signature Date

Printed Name Signature Date



Department of Energy

Washington, DC 20585

QA: QA

OCT 18 2002

K. G. Hess
Bechtel SAIC Company, LLC
1180 Town Center Drive, M/S 423
Las Vegas, NV 89144

ISSUANCE OF DEFICIENCY REPORT (DR) BSC(O)-02-D-188 RESULTING FROM AN OBSERVATION BY WILLIAM J. BOYLE

Enclosed is DR BSC(O)-02-D-188 generated as a result of an observation.

Please provide a response to this deficiency that meets the applicable requirements of Administrative Procedure (AP) 16.1Q, *Management of Conditions Adverse to Quality*. Send the original of your response to Deborah G. Opielowski, Navarro Quality Services, P.O. Box 364629, Mail Stop 455, North Las Vegas, Nevada 89036-8629. Initial response to the DR is due ten working days from the date of this letter. Any extensions to this due date must be requested in accordance with AP-16.1Q.

If you have any questions, please contact either James Blaylock at (702) 794-1420 or William J. Glasser at (702) 794-5014.

James Blaylock
R. Dennis Brown, Director
Office of Quality Assurance

OQA:JB-0100

Enclosure:
DR BSC(O)-02-D-188



OCT 18 2002

cc w/encl:

N. K. Stablein, NRC, Rockville, MD
Robert Latta, NRC, Las Vegas, NV
G. K. Beall, BSC, Las Vegas, NV
D. T. Krisha, BSC, Las Vegas, NV
N. H. Williams, BSC, Las Vegas, NV
W. J. Glasser, NQS, Las Vegas, NV
D. G. Opielowski, NQS, Las Vegas, NV
J. R. Dyer, DOE/YMSCO, Las Vegas, NV
D. G. Horton, DOE/YMSCO, Las Vegas, NV
W. J. Boyle, DOE/YMSCO, Las Vegas, NV
C. E. Hampton, DOE/YMSCO, Las Vegas, NV
J. M. Replogle, DOE/YMSCO, Las Vegas, NV
B. M. Terrell, DOE/YMSCO, Las Vegas, NV

Submittal Page 1 of 2

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.8. ☒ DEFICIENCY REPORT
☐ CORRECTIVE ACTION
REPORT
NO. BSC(0)-02-D-188
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)

AP-7.5Q Revision 1 ICN0, effective date 7/1/02

2. Related Report No.:

N/A

3. Responsible Organization:

BSC General Manager

4. Discussed With:

(in June) (in Aug.) (in Sept.)
Dennis Sorensen, Don Nitti, Rob Howard

5 Requirement:

The procedure requires the following: 5.2 DELIVERABLE SUBMITTAL, 5.2.1 Requester, c) Prepare a transmittal letter with the following information: 8) A listing of open Condition/Issue Identification and Reporting/Resolution System (CIRS) items related to the deliverable and/or associated work, or a statement that there are no open CIRS items related to the deliverable and/or associated work.

In addition, the procedure requires the following of Review Coordination: 5.2.2 RC: a) Return any incomplete deliverable packages to the Requester and inform the Requester of the reason or justification for not processing the deliverable package.

6. Description of Condition:

In June, two non-Q deliverables, ESS460000D and ESS450000D from the BSC ES&H organization came to OLRC with transmittal letters that did not have the required statement about CIRS items cited in box 5 above. At OLRC's request, BSC sent a corrected letter. I did not file a CIRS item and I am not aware that anyone else did so.

In August, another non-Q deliverable, SP8110000D, this from the LA Project came to OLRC with a transmittal letter that also did not have the required statement about CIRS items. At OLRC's request, BSC sent a corrected letter and filed a CIRS item about the procedural noncompliance with respect to the transmittal letter.

In September, a Q deliverable, PA0112900D, this from the PA Project came to OLRC with a transmittal letter that also did not have the required statement about CIRS items. OLRC And the PA Project have discussed the issue, and BSC is in process of sending a corrected letter and filing a CIRS item about the procedural noncompliance with respect to the transmittal letter.

(continued)

Has work been stopped? ☐ Yes ☒ No

7. Initiator.

WILLIAM BOYLE *William Boyle* 9/24/02
Printed Name Signature Date

9. Does a stop work condition exist?

☐ Yes ☐ No ☒ N/AIf Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:

NONE

11. QA Review:

WILLIAM J. GLASSER *William J. Glasser* 10/8/02
Printed Name Signature Date

12. Response Due Date:

10 Working Days after Issuance

13. QAM Issuance Approval:

Printed Name R. Dennis Brown Signature *James Blaylock for* Date 10/17/02
~~Ram B. Murthy~~

14. Corrective Actions Verified/Closure

QAR Printed Name Signature Date

15. QAM Closure Approval.

Printed Name Signature Date

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☒ DR/CAR/QO
☐ SWO

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CONDITION ADVERSE TO QUALITY CONTINUATION PAGE

6. Description of condition (continued)

In addition to these three separate organizations being in noncompliance, on at least the four occasions the Document Control group of the CIO was in noncompliance with the requirement cited above that it return any incomplete package.

This is filed as a DR and not a Quality Observation because the noncompliance is not isolated, a requirement to be a QO. In addition, this happened on 4 consecutive deliverables. It is quite possible it has happened on other deliverables, including Q ones. Whether or not this happened with other deliverables can only be determined by examination of other deliverables.

The Responsible Organization was identified as the BSC General Manager because that is the organization that has responsibility for all four of the organizations, Document Control, ES&H, LA Project, and PA Project that were in noncompliance.